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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,252	04/12/2001	Regine Helibronn	100564-00044	5869
6449	7590	11/15/2005	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/720,252	<b>Applicant(s)</b> HELIBRONN, REGINE	
	<b>Examiner</b> David Guzo	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 60-81 is/are pending in the application.
- 4a) Of the above claim(s) 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61-69, 72 and 77-79 is/are rejected.
- 7) ☒ Claim(s) 70-71, 73-76 and 80-81 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **Detailed Action**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/31/05 has been entered.

### **35 USC 102 Rejections**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61-64, 67-68, 72 and 77-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Dong et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicant traverses this rejection by asserting that:

- 1) Dong does not disclose a recombinant herpes virus containing AAV rep and AAV cap genes each operatively linked to a promoter within an expression cassette;
- 2) Dong does not disclose that such cassette is integrated into a non-essential region of the recombinant herpes virus genome; and

3) Dong does not state or imply that even if there were such a construct, and he does not, it would be expected to show no visible reversion to the corresponding herpes virus sequence lacking the rep and cap gene sequence under replication conditions described by applicant.

Applicant's arguments filed 8/31/05 have been fully considered but they are not persuasive. With regard to the first point of applicant's arguments, Dong et al. (see pages 7, 9, 30, Example VI, etc.) Dong et al. provides detailed teachings on how to generate a recombinant herpes viral vector (based upon recombinant HSV vector R7020) comprising the AAV rep and cap genes operably linked to a promoter(s) for expression. The protocol uses a well known and characterized HSV vector (R7020) and Dong et al. teaches that well known recombinant protocols previously used to generate recombinant herpes viral (HSV) vectors (Dong et al. cites references to Mocarski et al. (1980) and Post et al. (1981)) can be used to generate recombinant herpes viral vectors comprising the AAV rep and caps genes. Applicant has provided no evidence, other than unsupported assertions, that the skilled artisan, at the time the invention described by Dong et al. was made, would not have been able to reduce to practice the claimed herpes viral vectors.

With regard to the second point of applicant's arguments, Dong et al. recites in Example VI (page 44) that the rep-lip-cap genes are inserted into either of two non-essential regions of the R7020 HSV genome which can be at the site of the deleted tk gene or between the inserted tk gene and the HSV-2 DNA sequences. Applicant is

Art Unit: 1636

clearly incorrect in asserting that Dong et al. does not teach an AAV expression cassette integrated into the genome of the herpes viral vector.

With regard to the third point of applicant's arguments, applicants provide no evidence that AAV rep-cap genes integrated into a R7020 herpes viral genome (or indeed any other herpes viral genome) would show any greater propensity to be excised from the genome under viral replication conditions compared with the instantly disclosed herpes viral vectors. Again, applicant is proffering unsupported assertions without any supporting evidence. Given the teachings of Dong et al., said unsupported assertions cannot be considered persuasive. The rejection therefore stands.

### **35 USC 112, 2<sup>nd</sup> Paragraph Rejections**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 65, 66, 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 65 is vague in that it recites the "non-essential" herpesviral UL9 gene. An examination of the prior art indicates that the UL9 gene is essential for replication of herpesviral DNA *in vivo*. It is unclear why applicant believes this gene is non-essential.

Claim 66 is vague in that there is no antecedent basis for the term "the expression vector" in claim 61.

Claim 69 is vague in that there is no antecedent basis for the term "The rHSV" in claim 61.

### **Duplicate Claims**

Claim 80 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 69. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, both claims read on the same deposited biological material (ECACC Accession Number V97111302).

### **Claim Objections**

Claim 81 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 81 is dependent from Claim 80, which reads on the specific HSV vector deposited under ECACC Accession Number V97111302. Claim 81 merely recites a method by which the deposited vector is made and does not further limit the properties of the vector itself. Viewed another way, it can be considered that claim 81 broadens the scope of claim 80 in that the recited process step involves insertion of an expression cassette comprising "a promoter" (i.e. any promoter) operably linked to the AAV rep and cap genes. This is

Art Unit: 1636

broader than the specific promoter operably linked to the rep and cap genes in the deposited vector.

### **Miscellaneous**

Claim 77 has been amended to depend from a higher numbered claim. This is improper as claims should depend from earlier numbered claims. The dependency will be corrected by the examiner prior to allowance.

Any rejections not repeated in this Office Action is withdrawn.

Claims 70-71, 73-76 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone

Art Unit: 1636

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
November 9, 2005

  
DAVID GUZO  
PRIMARY EXAMINER